



hm 850 DC-V

Microprocessor-controlled rotary sealer with printer
for the packaging of sealable pouches and reels (SBS)
(Validatable process in accordance with EN ISO 11607-2)

hAWO

hawomed

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(Validatable process in accordance with EN ISO 11607-2 / The device conforms to the requirements of DIN 58953-7:2008)

The highest goal of every packaging system for medical devices, which are terminally sterilized, is the assurance of sterility until the products are used on the patient.

Validation

The validation of packaging processes is crucial to ensure that sterile barrier system integrity is attained and will remain so until opened by the users of sterile medical devices.¹

The new standard stipulates a packaging process that can be validated and is reproducible. For the sealing of a preformed sterile barrier system (SBS), e.g. sealable pouches and reels, only those processes that can be validated in accordance with EN ISO 11607-2 are recommended.

The standard additionally requires that the critical process parameters (at least temperature and contact pressure) are controlled, monitored and routinely documented.

A warning system and machine stop must be activated in the event that critical process parameters exceed predetermined limits.

EN ISO 11607-2 conformity

- Internal control and monitoring of the critical process parameters (temperature and contact pressure)
- Warning system and machine stop in case the critical parameters exceed predetermined limits
- Integration with external batch documentation system e.g. hawotest ht 180 PT-USB

The device thereby fulfills all necessary requirements for process validation according to EN ISO 11607-2 as well as the therefrom resulting specifications of the German Society for Sterile Supply DGSV detailed in the 'Guideline for the Validation of the Sealing Process'.

hawoflex™ sealing system

The patented hawoflex™ sealing system accommodates every material. Therefore a flawless, full-area sealing seam can also be achieved with materials of varying thickness.² The unique design of the hawoflex™ sealing seam guarantees an optimum seal security and sealing seam strength.

hm 850 DC-V is appropriate for the following packaging materials:³

- Sealable pouches and reels according to EN 868-5 and EN ISO 11607-1 (as well as gusseted pouches and reels)
- Tyvek®, 1059B, 1073B and 2FS
- Sealable paper pouches in accordance with EN 868-4
- Aluminum-laminate film

Simple data input and programming

The large and clearly laid out integrated keyboard of the hm 850 DC-V makes menu navigation and data input exceptionally simple. Information is clearly and precisely presented on the well laid out and backlit LCD display.

hm 850 DC-V with roll conveyor hm 500 RT (optional)



Documentation of the critical process parameters

The critical process parameters of temperature and contact pressure are controlled and monitored directly by the device. For long-term documentation the device hm 850 DC-V is compatible with additional systems:

1. ht 180 PT-USB

The hawotest-device ht 180 PT-USB is a mobile process documentation system. It automatically receives the critical process parameters as well as further relevant protocol data (date/time, machine number, personnel number, etc.). The data is then saved on a USB stick and transferred to a PC. The data is archived by means of a digitally signed and coded PDF document directly on the PC.

2. Batch documentation systems

The devices allow a direct connection to a batch documentation system through an interface.⁴

Integrated matrix printout

The following information can be printed directly on the paper side of the packaging:

- Packaging date (various date formats Y/M/D, Y/M, D/M/Y, M/Y, M/D/Y, Y)
- Expiry-date with automatic update
- Personnel name and number
- Batch number
- CE sign with corresponding text for medical product classification (e.g. CE 123)
- Device number/Serial number
- Piece counter
- An additional freely programmable text

Additional printer functions

- Symbols according to EN 980
- 3 pre-programmable expiry dates
- Setting for the print-out start margin from packaging edge
- Text size variable
- Print image 180 rotation (upside down)
- Printer can be turned on and off
- Simple ink ribbon change from the front side of the device

Seal Check function

The Seal Check function makes it possible to print the critical process parameters directly on the packaging. With the hawotest Seal Check indicator it is possible to confirm that the EN ISO 11607-2 recommended seal seam quality properties have been achieved:

- Intact sealing for a specified seal width
- No channels or open seals
- No punctures or tears
- No material delamination or separation

Deviations become visible by the indicator strip. The new standard DIN 58953-7:2008 requires above all the continual monitoring of these quality properties and therefore makes the daily test indispensable.

Standard conformity

- Quality management system in accordance with ISO 9001:2000 (QM certificate)
- Validatable process in accordance with EN ISO 11607-2
- Fulfillment of the requirements of the DGSV-Guideline for the Validation of the Sealing Process
- Fulfillment of the requirements of the RKI-Guidelines (Robert Koch-Institute)
- Included declarations of conformity:
 - CE
 - DIN 58953-7:2008
 - EN ISO 11607-2:2006

Security

- **Auto Switch-off:** Motor turns off when the front lid or casing is opened.
- **Device Protect:** In-feed guard prevents instruments from disrupting the sealing system.
- **Reverse Feed:** Function for removing instruments, which have been inadvertently inserted into the sealing area (manually).
- **Maintenance Control:** The devices provide automatic alerts when a service is due.
- **Autosave:** Parameter settings remain even after a power failure.
- **Proven Safety:** GS-certified safety by German test institution.

Additional functions

- 2-line back-lit LCD display
- Multiple language menu navigation
- RS 232 interface for bi-directional communication (USB and Ethernet optional)
- Operating time
- Piece counter (absolute and with reset function)
- Automatic start and print by photocell (opto-controller)
- Energy-saving function: device switches to an energy-saving stand-by mode after a pre-defined time (10 – 120 min)

Service

- Issuance of a calibration certificate for process-decisive parameters (optional)
- Seal seam strength test in accordance with EN 868-5 within validation (optional)

¹ According to the standard, validation must be carried out by the user in the installation location. The new guideline of the German Society for Sterile Supply (DGSV) for the Validation of the Sealing Process in accordance with EN ISO 11607-2 offers practical assistance (www.dgsv-ev.de/download:www.hawo.com).

² Various materials require multiple validations (see DGSV-Guideline)

³ Inappropriate for all thermoplastic foils (PE, PP, PVC)

⁴ The exact compatibilities have to be ascertained from the manufacturer

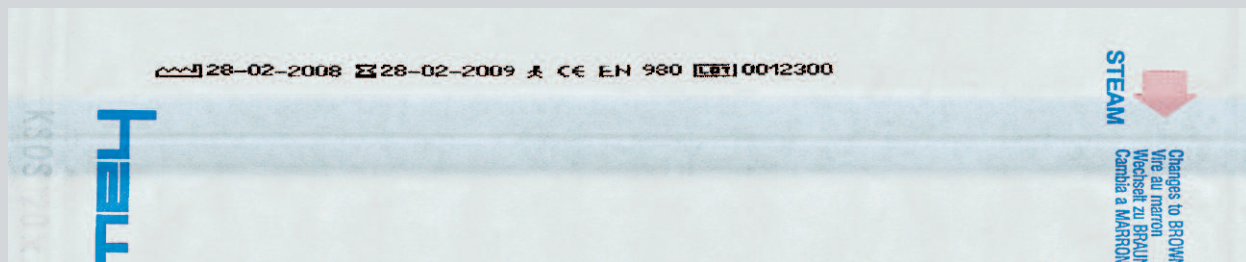


Technical Data

	hm 850 DC-V
Type of device	Rotary sealer
Control	Microprocessor
Process course	automatic/reproducible
Sealing speed	10 m/min (33 ft./min)
Sealing temperature	max. 220°C (max. 428°F)
Switch-off tolerance (DIN 58953-7:2008)	± 5°C (± 9°F) ± 2 – 5°C (± 3.6 – 9°F)/ab 2009
Contact pressure	100N
Seal distance from edge	0 – 35 mm (0 – 1.4 in.)
Seal seam width	12 mm (0.5 in.)/15 mm (0.6 in.) optional
Sealing system	hawoflex™, multi-line (optional)
Distance to medical product (DIN 58953-7:2008)	> 30 mm (1.2 in.)
Printout	single line
Print-out start margin from edge	continuous in mm
Mains connection	230 V, 50/60 Hz (EU), 115 V, 50/60 Hz (US), 100 V, 50/60 Hz (JP)
Critical parameters (controlled and monitored)	Temperature (variable) Contact pressure
Power	500 VA
Dimensions l x w x h	620 x 260 x 250 mm (24.4 x 10.2 x 9.8 in.)
Weight	23 kg (50 lb)
Casing cover	Stainless steel AISI 304
Casing base	Metal, powder-coated

Accessories

Roll conveyor	hm 500 RT	830 x 280 x 60 mm (32.7 x 11.0 x 2.4 in.)
Tray	hm 1000 T	850 x 280 x 60 mm (33.5 x 11.0 x 2.4 in.)
Process documentation system	ht 180 PT-USB	
Indicator system	Seal Check	



Seal Check An optimum sealing seam is guaranteed when the sealing temperature is correctly set and appropriate to the material to be sealed. Through the daily use of hawotest Seal Check indicators it can be proven that the quality properties recommended by the standards are achieved.

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Workstation

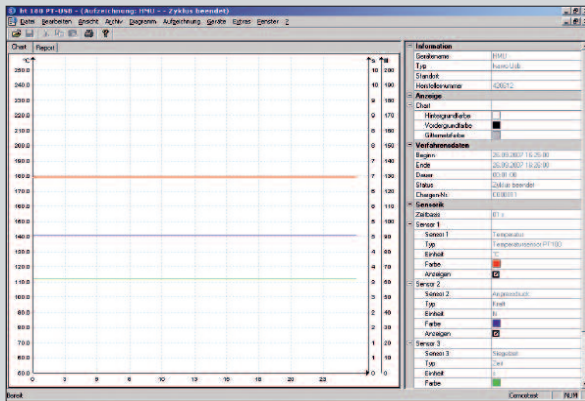
Workstations for the packaging of sterile barrier systems



hm 750 WST

The workstation hm 750 WST consists of a mobile base (basic element) with an integrated film roll holder, cutting device, storage baskets and consoles for sterilized bags (sterile bags), sterile containers and a generous work table.

Mobile table			hm 750 TF
Roll holder with cutting device			hm 750 RS
Trays	(w x d x h)		
2 items	270 x 570 x 270 mm	hm 500 K	(10.6 x 22.4 x 10.6 in.)
5 items	150 x 220 x 125 mm	hm 200 K	(5.9 x 8.7 x 4.9 in.)
Holder for sterile goods containers			
3 items	290 x 640 x 80 mm		(11.4 x 25.2 x 3.1 in.)
Holder for sterile goods packets			
2 items	255 x 410 x 75 mm		(10.0 x 16.1 x 3.0 in.)
2 items	205 x 320 x 75 mm		(8.1 x 12.6 x 3.0 in.)
Book ends	2 items	170 x 290 x 180 mm	(6.7 x 11.4 x 7.1 in.)
Overall dimensions		1500 x 800 x 1800 mm	(59.0 x 31.5 x 70.9 in.)
Total weight		105 kg	(232 lb)



ht 180 PT-USB

System for the documentation of the sealing process by USB-Stick (EN ISO 11607-2)





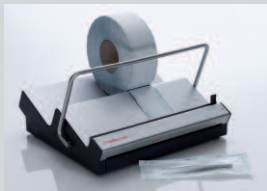
hawomed

Sealing devices and accessories for sterile goods packaging in clinics, central sterilization departments (CSSD) and the medical industry



hawotest

Testing systems for the validation (Operational and Performance Qualification) of heat sealing processes



hawodent

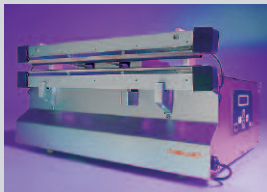
Sealing devices and accessories for sterile goods packaging in dentists' and doctors' surgeries

See also: www.generationeasy.com



hawoplast

Plastic film welding devices for industrial packaging



hawovac

Vacuum impulse sealers for industrial and medical packaging



hawopack

Packaging machines for clothes and linen for laundries, dry cleaners and the fashion industry

Subject to technical alterations

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hawo

hawo GmbH · Obere Au 2-4 · 74847 Obrigheim / Germany
T +49 (0)6261 9770-0 · F +49 (0)6261 9770-69
info@hawo.com · www.hawo.com